In the United States Court of Federal Claims

OFFICE OF SPECIAL MASTERS

No. 19-1413V

UNPUBLISHED

TANDY THOMAS, Petitioner, v. SECRETARY OF HEALTH AND HUMAN SERVICES, Respondent.	Chief Special Master Corcoran Filed: September 7, 2022 Special Processing Unit (SPU); Dismissal; Onset; Influenza (Flu) Vaccine; Guillain-Barré Syndrome (GBS)

Eric Grantham, Stipe Law Firm, Oklahoma, McAlester, OK, for Petitioner.

Steven Santayana, U.S. Department of Justice, Washington, DC, for Respondent.

DECISION DISMISSING CASE[1]

On September 13, 2019, Tandy Thomas filed a petition for compensation under the National Vaccine Injury Compensation Program, 42 U.S.C. §300aa-10, *et seq.*[2] (the "Vaccine Act"). Petitioner has alleged that he suffered Guillain-Barré syndrome ("GBS") as a result of an influenza ("flu") vaccine administered on October 3, 2018. Petition at 1. The case was assigned to the Special Processing Unit ("SPU") of the Office of Special Masters.

[1] Although I have not formally designated this Decision for publication, I am required to post it on the United States Court of Federal Claim's website because it contains a reasoned explanation for the action in this case, in accordance with the E-Government Act of 2002. 44 U.S.C. § 3501 note (2012) (Federal Management and Promotion of Electronic Government Services). **This means the Decision will be available to anyone with access to the internet.** In accordance with Vaccine Rule 18(b), Petitioner has 14 days to identify and move to redact medical or other information, the disclosure of which would constitute an unwarranted invasion of privacy. If, upon review, I agree that the identified material fits within this definition, I will redact such material from public access.

[2] National Childhood Vaccine Injury Act of 1986, Pub. L. No. 99-660, 100 Stat. 3755. Hereinafter, for ease of citation, all section references to the Vaccine Act will be to the pertinent subparagraph of 42 U.S.C. § 300aa (2012).

On September 14, 2020, Petitioner was ordered to show cause why this case should not be dismissed, because it appeared that the onset of his symptoms fell outside of the Table claim's defined timeframe. ECF No. 23. In reaction, Petitioner filed his response ("Response") on November 16, 2020. ECF No. 25. Respondent filed his reply ("Reply") on January 8, 2021. ECF No. 26.

For the reasons discussed below, this claim is hereby **DISMISSED**.

I. Relevant Procedural History

As noted, the case was filed in the fall of 2019. ECF No. 1. On August 10, 2020, Respondent filed a Rule 4(c) Report challenging Petitioner's right to compensation. ECF No. 22. In particular, Respondent asserted that Petitioner could not meet the requirements for a flu-GBS Table claim, because Petitioner's medical records indicated that the onset of Petitioner's neurological symptoms occurred more than a month *prior* to Petitioner's October 3, 2018 flu shot. Res. Report at 7-8.[3]

I issued an Order to Show Cause directing Petitioner to explain why his Table claim (plus any potential non-Table claim) should not be dismissed. ECF No. 23. The parties have now briefed the matter as indicated above, and this case is ripe for a determination.[4]

II. Authority

Before compensation can be awarded under the Vaccine Act, a petitioner must demonstrate, by a preponderance of evidence, all matters required under Section 11(c)(1), including the factual circumstances surrounding his claim. Section 13(a)(1)(A). In making this determination, the special master or court should consider the record as a whole. Section 13(a)(1). Petitioner's allegations must be supported by medical records or by medical opinion. *Id.*

To resolve factual issues, the special master must weigh the evidence presented, which may include contemporaneous medical records and testimony. *See Burns v. Sec'y of Health & Human Servs.,* 3 F.3d 415, 417 (Fed. Cir. 1993) (explaining that a special master must decide what weight to give evidence including oral testimony and

[3] Respondent also argued that Petitioner does not meet the Table criteria for acute inflammatory demyelinating polyneuropathy, acute motor axonal neuropathy, or acute motor and sensory neuropathy because he "did not have a monophasic illness pattern or a subsequent clinical plateau." Res. Report at 8. However, because I am resolving the claim based on the issue of onset, I do not also decide this fact issue.

[4] Six months after Respondent's Reply, on July 8, 2021, Petitioner filed an affidavit and letter from his primary care physician as Exhibits 15 and 16. ECF No. 27. Respondent filed a response to these exhibits on August 17, 2021. ECF No. 28.

contemporaneous medical records). Contemporaneous medical records are presumed to be accurate. *See Cucuras v. Sec'y of Health & Human Servs*., 993 F.2d 1525, 1528 (Fed. Cir. 1993). To overcome the presumptive accuracy of medical records testimony, a petitioner may present testimony which is "consistent, clear, cogent, and compelling." *Sanchez v. Sec'y of Health & Human Servs.,* No. 11–685V, 2013 WL 1880825, at *3 (Fed. Cl. Spec. Mstr. Apr. 10, 2013) (citing *Blutstein v. Sec'y of Health & Human Servs.,* No. 90–2808V, 1998 WL 408611, at *5 (Fed. Cl. Spec. Mstr. June 30, 1998)).

In addition to requirements concerning the vaccination received, the duration and severity of petitioner's injury, and the lack of other award or settlement,[5] a petitioner must establish that he suffered an injury meeting the Table criteria, in which case causation is presumed, or an injury shown to be caused-in-fact by the vaccination he received. Section 11(c)(1)(C).

The most recent version of the Table, which can be found at 42 C.F.R. § 100.3, identifies the vaccines covered under the Program, the corresponding injuries, and the time period in which the particular injuries must occur after vaccination. Section 14(a). Pursuant to the Vaccine Injury Table, GBS is compensable if it manifests within 3-42 days (not less than three days and not more than 42 days) of the administration of a flu vaccination. 42 C.F.R. § 100.3(a)(XIV)(D). (Further criteria for establishing a GBS Table Injury case be found under the accompanying Qualifications and Aids to Interpretation. 42 C.F.R. § 100.3(c)(15)).

Cases alleging a flu-GBS Table injury have often been dismissed for failure to establish proper onset. *See, e.g.*, *Randolph v. Sec'y of Health & Human Servs.*, No. 18-1231V, 2020 WL 542735, at *8 (Fed. Cl. Spec. Mstr. Jan. 2, 2020) (finding GBS onset at the earliest occurred 76 days post-vaccination, "well outside the 3 - 42-day window set by the Table for a flu-GBS claim"); *Upton v. Sec'y of Health & Human Servs.*, No. 18-1783V, 2020 WL 6146058, at *2-3 (Fed. Cl. Spec. Mstr. Sept. 24, 2020) (finding the petitioner did not establish the onset of his GBS within the 3 - 42-day time frame prescribed and thus did not establish a Table Injury).

III. Analysis

After reviewing the entire record, including all medical records, affidavits, Respondent's Rule 4(c) Report, and the parties' briefing, I have concluded that the onset of Petitioner's GBS more likely than not preceded his October 3, 2018 flu vaccination. I have specifically based my finding on the following evidence:

[5] In summary, a petitioner must establish that he received a vaccine covered by the Program, administered either in the United States and its territories or in another geographical area but qualifying for a limited exception; suffered the residual effects of his injury for more than six months, died from his injury, or underwent a surgical intervention during an inpatient hospitalization; and has not filed a civil suit or collected an award or settlement for his injury. *See* § 11(c)(1)(A)(B)(D)(E).

- Petitioner presented to his primary care provider, Dr. Chelsea Berges, on August 15, 2018. Ex. 3 at 37-39. Petitioner did not report neurological symptoms and he had a normal exam. *Id*.

- Petitioner received a flu shot on October 3, 2018. Ex. 2 at 2.

- Petitioner's insurance profile reflects that Petitioner filled a prescription for gabapentin on October 5, 2018 – two days post-vaccination. Ex. 2 at 2. The prescription was ordered by Dr. Berges and was noted to be for neuropathy. *Id*.

- Petitioner presented to Dr. Berges on October 16, 2018. Ex. 3 at 47-61. She noted that:

  "[Petitioner] has new onset peripheral neuropathy started in toes, then moved up legs, now in fingers as well.
  No vaccines prior
  Head is swimming
  Feels as though his legs are ascending weakness. No new meds or foods or shots (flu shot was after this started).
  Has some low back pain chronically
  b12 level normal (508)
  Tried gabapentin 100 TID, not touching it. Nothing seems to be helping.
  Seemed to start out of no where
  Started 3 months ago and is getting worse.

  Id. at 56. Dr. Berges' assessment included "other polyneuropathy," tick bite, GBS, and autoimmune disease. *Id*. at 57-58. She ordered bloodwork, which was normal, prescribed a Medrol Dosepak, advised Petitioner to increase the gabapentin dosage, and ordered a brain MRI. Id. at 57-61; 98-105.

- In her affidavit, signed on July 7, 2021, Dr. Berges acknowledges that the October 16, 2018 medical note indicates that "[Petitioner's] symptoms, which would eventually be diagnosed as being caused by [GBS], began three months prior to that visit and began before the flu shot was administered." Ex. 15 at 1. Dr. Berges further avers that after reviewing the records from both Petitioner's August 15 and October 16, 2018 appointments, "I am convinced that the progress note of October 16, 2018 is incorrect and should read [that Petitioner's symptoms began] two to three weeks before the visit." *Id*.

- In his second supplemental affidavit, signed on November 16, 2020, Petitioner stated that "[o]n October 20[,] 2018, I attended a car show in Lawton, Oklahoma. I drove there in my 1957 Chevrolet Belair." Ex. 13 at 1.

- Petitioner underwent a brain MRI on November 2, 2018. Ex. 3 at 112; Ex. 4 at 35. It revealed "no evidence for multiple sclerosis/demyelinating disease." *Id*.

- Petitioner presented to Dr. Kenneth Miller on November 8, 2018 with the chief complaint of leg and foot pain and an inability to move. Ex. 4 at 41. Dr. Miller noted that "[in] about late August [Petitioner] began to have pins and needles sensation in both toes and feet" and that while he was given a trial of gabapentin, "it induced drowsiness and he felt that he could not tolerate it." *Id.* Dr. Miller recommended that Petitioner report to the emergency room for further assessment and noted his impression of "[b]ilateral ascending peripheral neuropathy-sensory with a component of motor dysfunction. Possible [GBS] or toxic metabolic disturbance." Ex. 4 at 41, 43. Petitioner's treatment plan included intravenous immunoglobulin therapy (IVIG). *Id*. at 44.

- Petitioner presented to McAlester Regional Health Center's emergency department on November 8, 2018 with complaints of "progressive ascending weakness in his extremities bilaterally and difficulty walking." Ex. 4 at 28. Petitioner stated that these issues "started two months ago with numbness in his feet that turned into tingling and has progressed up to his hips." *Id*.

- Petitioner was admitted to the hospital on November 8, 2018 and was discharged on November 14, 2018 after completing his fifth dose of IVIG. Ex. 4 at 45-46. The discharge summary indicates that Petitioner's symptomology was consistent with GBS. *Id*. at 45.

- Petitioner received in-house rehabilitation services through McAlester Regional Health Center from November 14, 2018 through November 21, 2018. Ex. 4 at 126-129; 141-151; 153-160. The discharge summary indicates that Petitioner's diagnoses included GBS, muscle weakness, and coronary artery disease. *Id*. at 158.

- Petitioner presented to Dr. Miller on November 29, 2018 for a follow-up appointment. Ex. 3 at 86-91. Dr. Miller's impression included improving subacute GBS. *Id*. at 91.

- Petitioner returned to McAlester Regional Hospital's emergency room on December 15, 2018 with "worsening tingling in extremities and progressive weakness in legs" as well as shortness of breath, difficulty urinating and constipation. Ex. 4 at 246-248. Petitioner's physician's determined that he should be readmitted due to a reoccurrence of GBS and undergo another round of IVIG. *Id*. at 250. Petitioner was transferred to Hillcrest Medical Center for care because McAlester Regional Health did not have enough IVIG for treatment. Ex. 5-1 at 19.

- On December 16, 2018, Petitioner reported to Dr. Michael T. Cain, the consulting neurologist, that "2 month[s] ago beginning of 10/2018 he received the Flu vaccine, and within a week had a gradual ascending paralysis and respiratory difficulty." Ex. 5-1 at 26. Although Petitioner was assessed with "[f]lu vaccine-induced-[GBS], Acute Demyelinating Polyradiculoneuropathy" the neurologist also noted that "[Petitioner] has an intractable rather a [s]ubacute inflammatory demyelinating polyneuropathy (SIDP) a term typically used for GBS reaching its nadir between 4-8 weeks, which is compatible with the patient's history and disease process. The patient is also meeting the 2 month criteria for CIDP." *Id*. at 32.

- On December 18, 2018, the Petitioner was seen by Dr. Jaesun Kim, a neurologist. Ex. 5-1 at 40. Dr. Kim noted that based on the results of Petitioner's EMG/NCS study (performed on December 17, 2018), "I feel it is more likely [a] severe form of GBS rather than CIDP." *Id*. Dr. Kim's plan of treatment included the completion of IVIG and consideration of "starting/adding high dose steroid . . . if [Petitioner] shows another relapse or continuous progression suggesting CIDP over severe form of GBS." *Id*.

- Petitioner was discharged from Hillcrest Medical Center and transferred to the rehabilitation unit at McAlester Regional Hospital for "institution of rehabilitation" on December 23, 2018. Ex. 4 at 268, 275. Dr. Miller decided to start treating Petitioner with Plaquenil "with the thought process that this model of disease may be due to a blocking antibody production such as an IgE antibody." *Id*. at 276.

- Petitioner was discharged from McAlester's rehabilitation unit on January 10, 2019. Ex. 4 at 303-311. The discharge note indicates that Petitioner required "medical management by a physiatrist, as well as 24-hour rehabilitative nursing care." *Id*. at 309.

- Between January 10 and March 4, 2019, Petitioner resided at Walnut Grove Living Center for additional occupational therapy and physical therapy. Ex. 7 at 1. The

discharge summary indicates that Petitioner "worked well with therapy" and was being discharged home. *Id*.

- Between March 5 and June 28, 2019, Petitioner received home health services. Ex. 8. He was noted to wear leg braces but reported that "his condition continues to improve and is able to walk further distances without getting so tired." *Id*. at 250.

- Between April 25 and April 2017, 2019, Petitioner was admitted to the hospital due to abdominal cramping, projectile vomiting, and explosive diarrhea with concerns that his gastroenteritis would provoke his GBS. Ex. 4 at 503. A list of Petitioner's medical conditions included GBS. *Id*.

- Between May 11 and 12, 2019, Petitioner was admitted to the hospital due to recurring sharp pain in the left anterior thorax. Ex. 4 at 549-550. Petitioner was noted to suffer from GBS that began "in the late part of the fall of 2018." *Id*. at 549.

- In his second supplemental affidavit, signed on November 16, 2020, Petitioner avers that "after the flu shot of October 3, 2018, I began to experience numbness and neuropathy that quickly increased to weakness." Ex. 13 at 1. Petitioner further states that he "did experience some neuropathy in my feet and fingers before the flu shot on October 3, 2018; however, the neuropathy I experienced before was very mild and was not increasing in intensity." *Id*.

- In a letter dated July 7, 2021 and addressed "To Whom It May Concern," Dr. Berges summarizes Petitioner's course of treatment and states that "there is extensive data available proving [Petitioner's GBS] after influenza vaccine in 2018." Ex. 16.

A. Onset of Petitioner's GBS Likely Preceded Vaccination

The progress notes associated with Petitioner's initial post-vaccination medical appointments are especially probative, and strongly support the finding of a pre-vaccination onset. A review of these records reflects Petitioner's consistent report of neuropathy in his hands and fingers that began prior to his receipt of his flu shot. *See, e.g.*, Ex. 3 at 56 (October 16, 2018 medical note documenting that Petitioner's peripheral neuropathy symptoms began three months earlier); Ex. 4 at 41 (November 8, 2018 medical note reflecting that Petitioner "began to have pins and needles sensation in both toes and feet" in late August); Ex.4 at 28 (November 8, 2018 emergency room note indicating that Petitioner's presenting symptoms "started two months ago with numbness in his feet that turned into tingling and has progressed up to his hips.") Moreover, in his

affidavit, Petitioner acknowledges that he "did experience some neuropathy in [his] feet and fingers before the flu shot on October 3, 2018," though he explains that it was "very mild and was not increasing in intensity." Ex. 13 at 1.

I also give weight to records indicating that Petitioner filled a prescription for gabapentin on October 5, 2018 – just two days after his flu shot. It is apparent that it was prescribed in response to Petitioner's pre-vaccination neurological symptoms. *See, e.g.*, Ex. 2 at 2 (insurance profile indicating that Petitioner's gabapentin was for neuropathy); Ex. 4 at 41 (November 8, 2018 medical note indicating that Petitioner "began to have pins and needles sensation in both toes and feet" in late August and was given a trial of gabapentin.)

In his brief, Petitioner argues that the October 16, 2018 medical record documenting his appointment with Dr. Berges is inaccurate. He notes that Dr. Berges "first states that the problem is 'new onset' but later claims the problem started '3 months ago.'" Response at 12. Petitioner also argues that because Petitioner's back pain was also mentioned in this record, it is "unclear which of [Petitioner's] symptoms . . . is the new onset and which began three months earlier." *Id*. In addition, Petitioner notes that when he established care with Dr. Berges on August 15, 2018, there is no indication that he reported neurological symptoms. Response at 12. Petitioner concludes that "it is clear that the symptoms could not have started three months before October 16 when they did not exist on August 15, two months earlier." *Id*.

However, Dr. Berges has attempted to clarify the ambiguity of her October 2018 medical record. in her affidavit, she states that this progress note "should read [that Petitioner's symptoms, which would eventually be diagnosed as being caused by GBS began] two to thee weeks before the visit." Exhibit 15 at 1. Although this correction does not perfectly align with Petitioner's own contemporaneous reports of an onset in July or late August/early September of 2018, it does further substantiate that his symptoms began prior to his receipt of the flu shot.

Petitioner also points to statements made during his neurology consultation to support his assertion of a post-vaccination onset. During this December 16, 2018 appointment, Dr. Cain noted that Petitioner reported "2 month[s] ago beginning of 10/2018 he received the Flu vaccine, and within a week had a gradual ascending paralysis and respiratory difficulty." Ex. 5-1 at 26. In response, Respondent highlights Petitioner's own sworn testimony. Respondent notes that Petitioner stated that, "[o]n October 20, 2018, I attended a car show in Lawton, Oklahoma. I drove there in my 1957 Chevrolet Belair." Reply at 3, n. 4 (citing Ex. 13). Respondent further notes that, in his briefing, Petitioner acknowledged that this was over a three-hour drive. Reply at 3 (citing Response at 3 n.1).

Respondent asserts that "[i]f Petitioner had gradual ascending paralysis and respiratory difficulty within one week of vaccination, as reported in December 2018, it is not clear how he was able to make the trip to the car show. His supplemental affidavit therefore is inconsistent with the medical record on which he relied." Reply at 3, n. 4. This is a persuasive assertion.

Accordingly, the cumulative record evidence preponderantly supports onset of Petitioner's GBS before vaccination and Petitioner's Table Claim is dismissed.

B. Petitioner is Unable to Establish Actual Causation

Petitioner asserts that he should be allowed to proceed with a non-Table claim, and seeks leave to submit an expert report, if necessary. Response at 1, 15. Respondent opposes permitting the case to proceed in this manner. In addition to reiterating that the onset of Petitioner's neurologic symptoms preceded vaccination, Respondent also questions Petitioner's GBS diagnosis. Reply at 5.

However, because I have already found that Petitioner's neurologic symptoms predated vaccination, he is unable to prove the vaccine was causal. *See Johnson v. Sec'y of Health & Hum. Servs.*, No. 14-113V, 2017 WL 772534, at *16–18 (Fed. Cl. Spec. Mstr. Jan. 6, 2017) (noting that because petitioner's expert conceded she could not represent that autoimmune injury more likely than not began after vaccine, the "did cause" element could not be established).[6]

CONCLUSION

The evidentiary record does not support Petitioner's contention that he suffered a Table-GBS, or that the flu vaccine he received in October 2018 otherwise caused his GBS, because his neurologic symptoms more likely than not predated vaccination. Therefore, the petition is dismissed for insufficient proof. In the absence of a motion for review, the Clerk of the Court is directed to enter judgment accordingly.

[6] Petitioner did not allege a significant aggravation claim - that the flu vaccine worsened preexisting GBS. I therefore do not include an analysis herein of his success in so doing under the prevailing standard for such a claim. *Loving v. Sec'y of Health & Hum. Servs*., 86 Fed. Cl. 135, 144 (2009). Nor do I find that the record would support such a claim. While Petitioner briefly notes that "the neuropathy he experienced before the flu shot differed greatly in intensity from the neuropathy he experienced after the flu shot," this statement alone is insufficient to demonstrate a *vaccine-induced* worsening, as opposed to a progression that would be expected for any person suffering from GBS. The record otherwise does not suggest that the vaccine worsened Petitioner's preexisting disease.

IT IS SO ORDERED.

s/Brian H. Corcoran
Brian H. Corcoran
Chief Special Master